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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,338	02/27/2002	Tomohiro Yasuda	HIRA.0027	8246
38327	7590	06/06/2005	EXAMINER	
REED SMITH LLP 3110 FAIRVIEW PARK DRIVE, SUITE 1400 FALLS CHURCH, VA 22042			MAHATAN, CHANNING	
		ART UNIT		PAPER NUMBER
				1631
DATE MAILED: 06/06/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/083,338	YASUDA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Channing S. Mahatan	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 24 March 2005.  
2a)  This action is **FINAL**.                  2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

- 4)  Claim(s) 1-9,11,12 and 16-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-9,11,12 and 16-18 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## **Application Papers**

- 9)  The specification is objected to by the Examiner.  
10)  The drawing(s) filed on 27 February 2002 & 24 March 2005 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

## **DETAILED ACTION**

### *REQUEST FOR CONTINUED EXAMINATION*

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 24 March 2005 and the amendment to the specification filed on 07 December 2004 has been entered.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-9, 11, 12, 16-18. Claims 10 and 13-15 have been canceled.

### **Claims Rejected Under 35 U.S.C. § 101**

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

### *USE CLAIM*

Claims 16-18 are rejected under 35 U.S.C. § 101 because the claimed recitation of the use (i.e. "is used") of "greedy algorithm" "to compare the similarity between the sequence adjacent to the aligned window of said first nucleic acid base sequence with a sequence adjacent to the aligned window of said second nucleic acid base sequence"(claim 16)/"compare the consensus and the second sequence"(claims 17 & 18), without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 U.S.P.Q. 678

(Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 U.S.P.Q. 475 (D.D.C. 1966).

### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### *NEW MATTER*

Claim 12 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 12 recites the language “any entry in said table is removed if a number of entries sharing an identical key therein is more than a previously specified number”. Note the ‘ADVISORY ACTION’, mailed 21 January 2005, indicated that the above language appears to be absent from the specification and would result in a 35 U.S.C. 112 1<sup>st</sup> Paragraph ‘*NEW MATTER*’ Rejection. Applicants’ ‘RESPONSE’, filed 07 December 2004, indicated support for the amendment to claim 12 can be found on page 14-15 which states:

“After entering the partial sequences from the input sequences, every entry which corresponds to a key having the frequency of occurrence beyond a parameter F (described later) given by the user is deleted from the fixed-length partial sequence table 103. Generally, a nucleic acid base sequence often includes repeated sequences, so that it is expected that a lot of matching between partial sequences of the lengths s which are independent of the true overlap between input sequences may be found. Therefore, this processing intends to delete an entry corresponding to a key whose frequency of occurrence is extremely high.” (page 14, line 25 to page 15, line 5).

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However, there is no apparent support for the broadly encompassing language “sharing an identical key” and therefore such limitation is considered NEW MATTER. Note: If it is Applicants’ intent that instant claim 12 be representative of the language “a key having the frequency of occurrence beyond a parameter F” to be deleted/removed in said table; the claim as written is not indicative of this.

*LACK OF ENABLEMENT*

Claims 1-9, 11, 12, 16-18 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims contain the limitation/step for “comparing” in order to determine whether nucleic acid base sequences/consensus sequences are to be assembled, wherein the specification and Applicants arguments appear to require the reference to enable the concept.

Applicants contend on page 10 (lines 12-30) in the ‘*RESPONSE*’, filed 24 March 2005, that the specification provides ample recitation for “greedy alignment algorithm” and cite the following portion of the specification:

“When it has been found that a partial sequence 106 of a certain input sequence completely matches with a sequence defined by a fixed length window 105 as a result of referring to the table, whether it is included or not in the same cluster is verified by the detailed comparison of the sequences at the overlapping portion. Then members are included in the cluster one after another, based on a greedy algorithm. (page 12, lines 20-26 of the Specification)

“In this sequence comparison, a position of the exact matching whose length is between the consensus sequence and the input sequence is apparent, so that a high speed algorithm described in Zhang, Z. et al., J. Comput. Biol., 7(1-2): 203-14, 2000 is used.” (page 16, lines 5-9 of the Specification)

Applicants further contend on page 10, lines 31-35 of the ‘*RESPONSE*’, filed 24 March 2005, that the terms “greedy algorithm” and “high speed algorithm” are identical.

Thus, based upon the specification and Applicants' arguments the required procedures for "comparing" (as recited in the instant claims) appears to be an attempt to incorporate essential subject matter into this application by reference to the "Zhang et al.". Such incorporation is improper because the comparison procedures (i.e. greedy algorithm/high speed algorithm) described in "Zhang et al." are considered essential material for comparing nucleic acid base sequences/consensus sequences and to then determine whether these nucleic acid base sequences/consensus sequences should be assembled. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicants are required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 C.F.R. § 1.57(f).

**Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, 12, 16-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*VAGUE AND INDEFINITE*

Claims 1, 2, and all claims dependent therefrom recite the step "assembling said first nucleic acid base sequence and said nucleic acid base sequence if the sequence adjacent to the aligned windows are similar"(claim 1)/"if similar assembling said consensus sequence and second nucleic acid base sequences..."(claim 2) which is considered vague and indefinite. The term "similar" implies an unclear range values or set of criteria that Applicants regard to establish this "similarity" and to thereby assemble the first and second nucleic acid sequences.

Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 5 and all claims dependent therefrom recite the limitation "fixed-length partial sequence" which is considered vague and indefinite. As previously indicated (Refer to '*FINAL OFFICE ACTION*', mailed 07 September 2004) the above limitation implies a range or criteria defining a fixed-length partial sequence. Applicants' have pointed to the following portion of the specification as providing ample description in choosing:

"Next, the process proceeds to Step 202 in FIG. 2 and constructs a fixed-length partial sequence table 103. When constructing the fixed-length partial sequence table 103, partial sequences 102 having a length of s at the head and tail end among all the input sequences 101 is entered into the table 103 as shown in FIG. 4. If the length s of the partial sequence is taken longer, the probability of occurrence of coincidence between the lengths s can be decreased regardless of the presence of a true overlap between the input sequences, so that the processing time can be shorten. However, if the length s of the partial sequence is excessively taken too long, the sensitivity for searching for an overlap will become lower. In the present invention, the value s has a lower limit which is represented by an expression (1) described below, in order to shorten the processing time.

$$s \geq \frac{1}{2} \log \frac{KN}{c} \quad \dots(1)$$

In the above expression (1), N is the number of input sequences, K is the number of partial sequences selected from each sequence, and c is a parameter given by a user and is an amount specifying an upper limit of the expected value of the number of exact matching which can be found after each reference to the fixed-length partial sequence table 103 regardless of the presence of the true overlap between the input sequences. If the value c becomes larger, the value s can be smaller. Thus the length of the partial sequence becomes shorter, so that the sensitivity for

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searching for an overlap can be higher. However, the computing time for processing the coincidence matching becomes longer, so that the processing speed decreases. In this specification, the base of logarithms is 2." (page 13, line 9 to page 14, line 8).

However, the cited portion of the specification fails to provide an adequately reasonable understanding of what Applicants' regard the above language to encompass. For instance, is a "fixed-length partial sequence": 1) one nucleotide long; 2) two nucleotides long; etc? Applicants' can resolve this issue by particularly pointing out what defines a "fixed-length partial sequence". Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 16-18 provides "a greedy algorithm is used to compare the "similarity between the sequence adjacent to the aligned window of said first nucleic acid base sequence with a sequence adjacent to the aligned window of said second nucleic acid base sequence"(claim 16)/"compare the consensus and the second sequence"(claims 17 & 18), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Clarification of the metes and bounds, via clearer claim language, is requested.

#### *EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: CSM

Date: May 27, 2005

Ardin H. Marschel 5/30/05  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER